

NATURE OF CHARGE: Misbranding, Section 502 (j), the *crystalline sulfanilamide* would be dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in the labeling, "Directions * * * After controlling hemorrhage, sprinkle powder in wound, covering the depth and injured surfaces lightly, then cover with sterile dressing and bandage."

DISPOSITION: August 23 and December 13, 1946. No claimant having appeared, judgments of condemnation were entered and the lot of 800 packages was ordered destroyed, and the lot of 13,500 packages was ordered delivered to the Department of Hospitals of the City of New York.

DRUG CONTAINING PENICILLIN DISPENSED WITHOUT PRESCRIPTION OF PHYSICIAN

2052. Action to enjoin and restrain the sale of misbranded Ledercillin-G Lozenges. U. S. v. Parkview Drug Co., Phil Small, John Small, and Harry Small. Consent decree granting injunction. (Inj. No. 141.)

COMPLAINT FILED: May 29, 1946, Western District of Missouri, against the Parkview Drug Co., a corporation, Kansas City, Mo., and Phil Small, John Small, and Harry Small, officers of the corporation.

NATURE OF CHARGE: Section 507. That the defendants had for a long time operated a chain of drug stores in Kansas City, Mo., and had been and were offering for sale at their drug stores, without the submission of a physician's prescription, a drug under the name *Ledercillin-G Lozenges* which contained penicillin. The complaint further alleged that the Federal Security Administrator had promulgated regulations for the certification of drugs composed wholly or partly of penicillin, which regulations provided that such drugs should be dispensed by or on the prescription of a physician, and that the defendants had on hand at the various stores a large stock of the drug which they were selling and intended to sell in the future.

PRAYER OF COMPLAINT: That a temporary restraining order be issued immediately without a hearing; that within 10 days after the granting of the restraining order a temporary injunction issue; and that after final hearing, defendants be permanently enjoined and restrained from sale of the article without a physician's written prescription.

DISPOSITION: October 1, 1946. The defendants having consented to the entry of a decree, the court issued an order permanently enjoining the defendants and their agents from the sale of any drug containing a derivative of penicillin without the written prescription of a physician.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

2053. Alleged misbranding of seconal sodium capsules and benzedrine sulfate tablets. U. S. v. Alfred R. Collins (Collins Bros., Walgreen Agency Drug). Plea of not guilty. Tried to the court. Verdict of not guilty. (F. D. C. No. 17860. Sample Nos. 26067-H to 26069-H, incl.)

INFORMATION FILED: August 12, 1946, Northern District of Texas, against Alfred R. Collins, trading as Collins Bros., Walgreen Agency Drug, Big Springs, Tex.

INTERSTATE SHIPMENT: Between the approximate dates of February 1944, and October 10, 1944, from Indianapolis, Ind., and Philadelphia, Pa., of a quantity of *seconal sodium capsules* and *benzedrine sulfate tablets*.

LABEL, WHEN SHIPPED: "500 Pulvules Seconal Sodium 1½ grs. * * * Caution: To be used only by or on the prescription of a physician * * * Eli Lilly and Company Indianapolis," or "250 Tablets 10 mg. Benzedrine Sulfate Tablets * * * Caution: To be used only by or on the prescription of a physician * * * Smith, Kline & French Laboratories Philadelphia, Pa."

NATURE OF CHARGE: That on or about March 16, 20, and 21, 1945, the defendant caused to be removed a number of tablets from bottles bearing the labels described above, repacked the tablets into unlabeled envelopes, and sold those tablets without a prescription.

The information charged further that the act of the defendant resulted in the misbranding of the articles in the following respects: Section 502 (f) (1),

the envelopes containing the articles bore no labeling containing directions for use; and, Section 502 (f) (2), they bore no labeling containing warnings against use in those pathological conditions and by children where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

It was charged also that the defendant's acts resulted in the misbranding of the *seconal sodium capsules* under Section 502 (d), in that the capsules contained in the envelopes contained a chemical derivative of barbituric acid, seconal, which derivative had been found, and by regulations designated as, habit forming; and the label of the article in the envelopes failed to bear the name and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

DISPOSITION: On October 9, 1946, the defendant having entered a plea of not guilty, the case came on for trial before the court. At the conclusion of the trial, the court handed down a verdict of not guilty.

2054. Misbranding of diethylstilbestrol tablets, elixir alurate, and ephedrine and amytal pulvules. U. S. v. Louis L. Patt (Courtesy Drug Store) and Al Defnet. Pleas of nolo contendere. Fine of \$200 against Louis L. Patt on count 1. Imposition of sentence against Louis L. Patt suspended on counts 2 and 3; sentence against Al Defnet suspended on all counts. Both defendants placed on probation for 1 year. (F. D. C. No. 20118. Sample Nos. 73926-F, 73934-F, 73975-F.)

INFORMATION FILED: April 24, 1946, District of Arizona, against Louis L. Patt, trading as the Courtesy Drug Store, Phoenix, Ariz., and Al Defnet, an employee.

INTERSTATE SHIPMENT: Between the approximate dates of May 29, 1944, and September 27, 1944, from Philadelphia, Pa., Nutley, N. J., and Indianapolis, Ind., of quantities of *diethylstilbestrol tablets*, *elixir alurate*, and (capsules) *ephedrine and amytal pulvules*.

PRODUCT: The drugs had been made for use exclusively by or on the prescription of a physician, and the labels bore the statement, "Caution: To be used only by or on the prescription of a physician." As a result the drugs were not required to comply with Section 502 (f) (1), which requires that adequate directions for use appear in the labeling.

LABEL, WHEN SHIPPED: "Diethylstilbestrol * * * Warning: This is a potent drug and serious consequences may result if used other than under constant medical supervision"; "Elixir Alurate * * * contains ½ gr. Allyl-Isopropyl-Barbituric Acid Warning: May Be Habit Forming"; or "Pulvules Ephedrine and Amytal Warning: May Be Habit Forming."

NATURE OF CHARGE: *Diethylstilbestrol tablets* and *elixir alurate*. On or about September 30 and October 13, 1944, while the drugs were being held for sale after shipment in interstate commerce, the defendants caused them to be sold, delivering them to the purchasers in the bottles labeled as indicated above, without a physician's prescription. The sale of the drugs by the defendants caused the exemption to expire and resulted in the misbranding of the drugs in violation of Section 502 (f) (1), since the bottles bore no labeling containing directions for use.

Ephedrine and amytal pulvules. On or About November 22, 1944, the defendants removed a number of pulvules (capsules) from the bottle and repacked them into an unlabeled cardboard box and sold them without a prescription. The acts of the defendants resulted in the drug being misbranded in violation of Section 502 (f) (1), since the cardboard box bore no labeling containing directions for use; and, Section 502 (f) (2), the labeling of the drug failed to bear adequate warnings against use in those pathological conditions where its use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form as are necessary for the protection of users.

DISPOSITION: On May 13, 1946, the defendant, Louis L. Patt, having entered a plea of nolo contendere, the court imposed a fine of \$200 on count 1, suspended imposition of sentence against him on counts 2 and 3 for 1 year, and placed him on probation for that period of time. On June 3, 1946, Al Defnet, having entered a plea of nolo contendere, imposition of sentence against him was suspended on all counts for 1 year, and he was placed on probation for that period.